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**SANDIA NATIONAL LABORATORIES
QUALITY ASSURANCE PROGRAM
for the
OFFICE of CIVILIAN RADIOACTIVE WASTE MANAGEMENT**

QAP 1-1

**ORGANIZATION and
QUALITY ASSURANCE PROGRAM**

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1.0 Purpose and Scope

This procedure prescribes the Sandia National Laboratories (SNL) Civilian Radioactive Waste Management (CRWM) Office of Science & Technology and International (OSTI) Program organizational structure, organizational interfaces, functional responsibilities, and levels of authority for achieving, maintaining, improving, assessing, and documenting quality. It also defines the requirements for the development, implementation, and continual improvement of the quality assurance (QA) program.

1.1 General

The SNL OSTI QA program applies to all work activities managed by the SNL OSTI Program. This program is structured to support nuclear waste activities conducted for the U. S. Department of Energy (DOE), as well as nuclear waste management and transportation related activities outside that scope. All personnel who works either directly or indirectly for the SNL OSTI program shall comply with the requirements of this procedure and other quality affecting procedures SNL designates applicable to their activities.

1.2 QA Requirements

QA requirements applicable to work activities shall be specified during the planning phase to ensure the development and implementation of effective controls so that items, processes, and services meet or exceed customer requirements. QA requirements shall be specified in work-specific planning documents (such as test plans).

2.0 Implementation Actions

2.1 Organizational Structure

The organizational structure of the SNL OSTI Program and component activities is formally documented in a the OSTI Quality Assurance Program Plan (QAPP) on file in the SNL Records Center and on the SNL OSTI On-line Web Site: www.nwmp.sandia.gov/onlinedocument.

The OSTI Project Lead has overall responsibility for the development and implementation of the SNL OSTI QA program. The OSTI Project Lead is responsible for defining, integrating, and ensuring effective implementation of QA activities throughout the SNL OSTI program.

The SNL OSTI program is structured such that the individual performing the work is responsible for achieving and maintaining quality; line management is responsible for evaluating quality; and independent assessors are responsible for independently assessing the quality of the work. Effective implementation of the SNL OSTI QA program is dependent upon the efforts of all levels of the SNL CRWM organization including the OSTI Project Lead, SNL Managers within the OSTI Mangement Team, and other Sandia managers, staff, and contractors assigned to perform OSTI work.

2.2 QA Program

2.2.1 Responsibilities

2.2.1.1 OSTI Manager Responsibilities

OSTI Managers shall provide the planning, organization, direction, control, resources, and support required to achieve OSTI objectives, and ensure that products meet customer expectations in a timely and cost effective manner. This requires effective planning, performing, assessing, and continuous improvement of work activities. Management responsibilities concerning quality include:

- Procedural Control of Activities - developing, implementing, and maintaining policies, plans, and procedures that control the quality of the work consistent with applicable upper-tier requirements.
- Qualification and Training - ensuring adequate technical and QA training is provided to personnel performing quality affecting activities.
- Compliance - ensuring compliance with applicable regulations and requirements.
- Records - ensuring personnel adhere to applicable procedures concerning the generation, identification, control, and protection of QA records.
- Stopping Work - exercising the authority and responsibility to stop unsatisfactory work.
- Corrective Action - identifying, controlling, investigating, reporting, correcting, and documenting quality problems and conditions adverse to quality in a timely manner.
- Personnel Management - identifying and defining organizational and individual responsibilities and authority for achieving and verifying quality, and ensuring each employee understands their responsibilities concerning the quality of their own work and for reporting potential or existing conditions adverse to quality to responsible management for evaluation and action. Management empowers employees by delegating authority and decision making to the lowest appropriate level in the organization.
- Assessing Quality - management is responsible for the achievement and assessment of quality for OSTI activities.
- Continuous Improvement - implementing actions to promote the continuous improvement of quality related processes.
- Control of internal and external interfaces.

2.2.1.2 OSTI QA Lead Responsibilities

The OSTI QA Lead supports line management and individuals in understanding, interpreting, and meeting QA requirements. The OSTI QA Lead shall have sufficient authority, access to work areas, and organizational freedom to identify quality problems, recommend solutions, verify implementation of solutions, and assure that unsatisfactory conditions are controlled until proper disposition has occurred.

The OSTI QA Lead shall:

- Have direct access to management at a level where appropriate action can be effective.
- Be sufficiently independent from cost and schedule considerations.
- Have the organizational freedom to communicate with other management positions.
- Have no other assigned responsibilities unrelated to the QA program that would prevent appropriate attention to QA matters.

The OSTI QA Lead shall ensure that the following QA functions are performed:

- Scheduling and conducting QA assessments.
- Maintaining liaison with customers and subordinate organizations.
- Preparing and reviewing procedures which implement SNL OSTI planning documents.
- Reviewing and approving QA assessments.
- Reviewing and approving supplier and subcontractor QA planning documents.
- Tracking quality indicators, performing trend analyses, and reporting QA problems.
- Processing documentation concerning conditions adverse to quality.
- Responding to changes in the DOE Quality Assurance Requirements Description (QARD) Document by reviewing the SNL OSTI QA Program Plan (QAPP) and applicable QAPs, and updating them as necessary.

2.2.1.3 Individual Responsibilities

Each individual is responsible for the quality of his/her work. All individuals are responsible for identifying potential and existing conditions adverse to quality, and reporting them through the SNL OSTI Corrective Action program outlined in QAP 16-1 Corrective Action.

2.2.2 Communication

All management levels shall establish and maintain channels of communication to provide timely dissemination of quality performance information addressing issues such as:

- The development and implementation status of the OSTI QA program,
- The status and resolution of significant quality problems,
- Lessons learned from significant quality problems, and adverse condition,
- Quality management practices and improvements, and trend analysis results.

2.2.3 Management Assessments

- Strategic planning
- Organizational interfaces
- Use of performance indicators
- Staff training and qualifications
- Supervisory oversight and support
- Employee knowledge, motivation, and morale
- Atmosphere of creativity and improvement
- Amount of mutual trust and communication among workers and organizations

2.2.3.1 General

Management assessments of the SNL OSTI QA program shall be conducted periodically, and reported at least annually. The purpose of these assessments is to evaluate the implementation of QA program elements and their effectiveness in meeting customer requirements and expectations for quality, and to identify specific areas of opportunity for management to improve the QA process.

Management assessments shall emphasize the use of human and material resources to achieve organizational goals and objectives.

Management assessments should include an evaluation of the effectiveness of the overall management system in meeting strategic goals, and identification and resolution of both systemic and

management issues, citing specific strengths and weaknesses affecting the organization's ability to improve quality.

Management assessments shall include direct participation by the OSTI Project Lead through the involvement and implementation of the assessment process.

2.2.3.2 Documentation

A written report recommending actions to improve the process shall be submitted to the OSTI Project Lead, with the results disseminated to all levels of management in the organization. A copy of the report will be submitted to the SNL Records Center.

2.2.4 Resolution of QA Disputes

2.2.4.1 Dispute Process

QA disputes involving the definition and implementation of QA program requirements shall be brought to the attention of the OSTI QA Lead and the responsible manager and, if not resolved, elevated to the OSTI Project Lead. When resolution cannot be completed at this level, the dispute shall then be elevated to the DOE OCRWM Office of Quality Assurance (OQA).

2.2.4.2 Documentation

The SNL OSTI QA Lead shall determine if the scope, magnitude, and possible effects of the dispute warrant documentation, and if so, ensure that a suitable record is submitted to the SNL Records Center.

2.2.5 Readiness Reviews

Readiness reviews are conducted at management's discretion to determine through examination and evaluation of objective evidence if prerequisites for achieving program objectives have been met before major planned or scheduled work is started.

3.0 Records

The following QA records, generated through implementation of this procedure, shall be prepared and submitted to OCRWM and a copy to the SNL Records Center in accordance with QAP 17-1 (Records):

QA Record

- Organizational Structure Description
- QA Dispute Records
- Quality Assurance Program Plan
- Management Assessment Reports

4.0 Appendices

Not Applicable. No forms or flow charts are used in conjunction with this procedure.